

## REMARKS

To summarize the status of this case, we note that claims 1-6 and 8-23 are pending. Claims 9-23 have been withdrawn by the Examiner as drawn to non-elected subject matter. The rejections of claims 1-7 under 35 USC §102(b) over Miettinen *et al.*, U.S. Patent No. 5,502,045 and Eugster *et al.*, CA 120:245603 set forth in Paper No. 2 at 6 appear to have been withdrawn. And, as discussed in more detail below, it appears that the 35 USC §102(b) rejection over Miettinen *et al.*, WO 92/19640 (International Application No. PCT/FI91/00139) (“Miettinen”) has been “maintained.” (Paper No. 6 at 2).

Claim 8 was rejected under 35 USC §112, second paragraph. (Paper No. 6 at 5). In making the rejection, the Examiner contended that “[c]laim 8 is improperly dependent on claim 1. ***Claim 8*** does not further limit ***claim 8***.” (*Id.*).

For the reasons set forth below, this rejection, respectfully is traversed.

Initially, we note that it appears that there is a typographical error in the rejection. It is assumed that the Examiner intended to state that “***Claim 8*** does not further limit ***claim 1***.” For purposes of this response, we will follow that assumption. If this assumption is incorrect, the Examiner is requested to clarify the rejection on the record.

For the convenience of the Examiner, claim 8 is reproduced below:

8. (Amended) A ***composition*** comprising a ***compound according to claim 1 in admixture with a second ester of a phytosterol and/or phytostanol***, wherein the second ester is the product of an esterification reaction between a phytosterol and/or phytostanol and (a) a fatty acid having less than 18 or more than 22 carbon atoms and at least three carbon-carbon double bonds and/or; (b) a fatty acid having from 18 to 22 carbon atoms and less than three carbon-carbon double bonds.

Thus, the *composition* of claim 8 contains at least two esters of a phytosterol and/phytostanol. In contrast, note that claim 1 recites “a compound.” It is respectfully submitted that the rejection fails to identify with particularity what it is about claim 8 that “does not further limit claim 1.” But that was the Examiner’s burden.

As is well settled, “[i]n rejecting a claim under the second paragraph of section 112, *it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to* ascertain the scope of protection defined by the claim when read in light of the supporting specification.” *Ex parte Cordova*, 10 USPQ2d 1949, 1950, and 1952 (B.P.A.I. 1989) and *Ex parte Balzarini*, 21 USPQ2d 1892, 1898 (B.P.A.I. 1991) (the Examiner did not give a reason *why*). Because the rejection does not explain *why* claim 8 does not further limit claim 1 or *why* one skilled in this art would be unable to ascertain the scope of the claim, as was required, the rejection is insufficient as a matter of law, and should be withdrawn.

As noted above, it appears that the rejection under 35 USC §102(b) over Miettinen has been “maintained.” (Paper No. 6 at 2). The purported rejection, however, states only that:

Claims rejected as being anticipated by WO 92/19640 lines 4-6, page 5; lines 8-37, page 6; *Claims 1, 5, and 6* is maintained

Claims are amended but *claims 1-7* are still considered anticipated, see lines 20-24, page 10; lines 22-30 page 9. (*Id.*).

The rejection provides nothing more.

Miettinen disclose a  $\beta$ -sitostanol fatty acid ester or fatty acid ester mixture that lowers serum cholesterol levels and processes for producing the ester or ester mixture. *See* Abstract. Miettinen further disclose:

In accordance with the invention, the  $\beta$ -sitostanol mixture, which contains campestanol approx. 6%, is esterified with *different* fatty acid ester mixtures by a commonly known chemical interesterification technique. A *methyl ester* mixture of the fatty acids of *any* vegetable oil can be used in the reaction. One example is a mixture of rapeseed oil and methyl ester, but *any* fatty acids which contain approx. 2-22 carbon atoms are useable. (Page 6, lines 24-34).

The process used to produce the “stanol fatty acid esters” in Miettinen is disclosed to include “no other substances other than free stanol, a fatty acid ester or a fatty acid mixture, and a catalyst.” (Page 6, line 35 - Page 7, line 2).

Initially, we note that the purported rejection is unclear as to which claims stand rejected under 35 USC §102(b) in view of Miettinen. In the rejection mailed February 14, 2000, it appears that *claims 1-7* were rejected. (*See*, Paper No. 2 at 6). The present rejection, however, states that “claims rejected as being anticipated by WO 92/19640 ... *Claims 1, 5, and 6* is maintained.” In the very next sentence, the Examiner asserts that “[c]laims are amended but *claims 1-7* are still considered anticipated.” In short, the Examiner appears to reject claims 1-7, then reject claims 1, 5, and 6, and then reject claims 1-7 again. As is well settled, an Applicant is not required to guess at what the rejection is. For this reason alone, the rejection should be withdrawn.

In addition to unambiguously identifying which claims are rejected, it is also the Examiner’s burden to make a rejection *and* to provide the “ground of rejection *fully and clearly stated*.” *See* MPEP §707.07(d) at 700-61 7th Ed. rev. 1 (Feb. 2000) (“*The pertinence* of each

reference, if not apparent, *must be clearly explained* and each rejected claim specified.”) 37 CFR § 1.104(c)(2), (“... the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, *clearly stating the reasons in support thereof.*”), 37 CFR §1.113(b), and MPEP § 706.02 at 700-9 (“The language to be used in rejecting claims should be *unequivocal.*”).

This rejection is in contravention of both the patent rules and PTO practice because (1) it requires the Applicants to guess which claims are under rejection (1-7 or 1, 5 and 6) and (2) it does not provide an explanation of the rejection (at most it simply lists page and line numbers for the asserted WO document). Where in the rejection is the clear explanation, the clear reasons, and the unequivocal language called for by the patent rules and the PTO’s own procedures? In sum, the rejection is clearly deficient as a matter of law and PTO practice. For this reason also, the rejection should be withdrawn.

In an effort to further prosecution, however, we will address the merits of the rejection to the best that we are able given the deficiencies noted above.

As noted above, in making the purported rejection, the Examiner only provides citations to Miettinen. The passages in Miettinen relied on by the Examiner are:

lines 4-6, page 5;

lines 8-37, page 6;

lines 20-24, page 10; and

lines 22-30, page 9. See Paper No. 6 at 2 and Paper No. 2 at 6.

As is fundamental, anticipation requires “identity of invention.” *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference *and arranged*

*as in the claim.* *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984).

As noted above, the rejection is nothing but a stringing together of random passages from Miettinen. The Examiner used four different passages found between pages 5 and 10 of Miettinen. Without any commentary or explanation from the Examiner as to how these citations fit together, the rejection is *prima facie* insufficient because it has not provided any evidence that the four separate citations cited are “arranged as in the claim.” For this additional reason, the rejection is insufficient as a matter of law, and should be withdrawn.

We also note that in our arguments presented in the RESPONSE TO OFFICE ACTION INCLUDING AMENDMENT mailed July 14, 2000 we asserted that “Miettinen fails to disclose eicosapentaenoic acid or docosahexaenoic acid, as required by claim 1 and, hence, all claims dependent therefrom. Therefore, Miettinen does not anticipate claims 1-6.” (See Page 10). The Examiner’s sole response to this is to “see the office action under 102 rejection where lines and cols were indicated.” (Paper No. 6 at 5). What was required, however, was that the Examiner “take note of the argument *and answer the substance of it.*” See MPEP §707.07(f).

It is not understood how the Examiner’s assertion “see the office action under 102 rejection where lines and cols were indicated” in any way *answers* our previous argument that Miettinen does not disclose eicosapentaenoic acid or docosahexaenoic acid, as required by claim 1 ... and therefore does not anticipate claims 1-6.” Accordingly, the Examiner’s guidance to “see the office action,” without more, is insufficient as a matter of law and PTO procedure. For this additional reason, the rejection should be withdrawn.

Notwithstanding the lack of an “answer” to our previous argument, we further note that the Examiner acknowledges in the present Office Action that the “[i]nstant claims *differ from the reference* [Miettinen] in claiming specific fatty acids *i.e.* docosahexaenoic acid and eicosapentaenoic acid where prior art teaches fatty acids especially containing approximately 2-22 carbon atoms.” (Paper No. 6 at 9). Given that the Examiner has acknowledged on the record that the “instant claims” differ from Miettinen, the rejection under 35 USC §102(b) is improper, and must be withdrawn.

Furthermore, should the Examiner contend that the disclosure in Miettinen that “*any* fatty acids which contain *approx. 2-22 carbon atoms* are useable” anticipates the recitation of docosahexaenoic acid and eicosapentaenoic acid in claim 1, we note that it is well settled that a genus does not *ipso facto* render a species anticipated. *See Corning Glass Works v. Sumitomo Elec. U.S.A.* 9 USPQ2d 1962, 1970 (Fed. Cir. 1989) and *In re Meyer*, 202 USPQ 175, 179 (C.C.P.A. 1979) (finding that prior art genus did not “identically disclose or describe, within the meaning of section 102” the claimed species “since the genus would include an untold number of species.”).

The rejection does not identify how many fatty acids are encompassed by the recitation of *any* fatty acid containing “approx. 2-22 carbon atoms” in Miettinen. The rejection does not address whether one would have “immediately envisaged” either docosahexaenoic acid or eicosapentaenoic acid as recited in the present claims from the genus of *any* fatty acid having 2-22 carbon atoms disclosed by Miettinen, and if so why. Nor does the rejection provide any evidence that members of such a genus would be closely related in structure, but for the number of carbon atoms. Thus, the rejection’s reliance on the recitation of a genus of fatty acids having approx. 2-22 carbon atoms is misplaced. For this reason also the rejection should be withdrawn.

In sum, for the reasons set forth above the rejection is insufficient as a matter of law and fact and should be withdrawn.

Claims 1-4 were newly rejected under 35 USC §102(b) as anticipated by Shimada *et al.*, *JAACS*, 76(6):713-716 (1999) (“Shimada”). (Paper No. 6 at 6). In making the rejection, the Examiner asserted:

See Table 3 on page 716 where esterification of sitosterol (which is phytosterol) are disclosed. Fatty acid is the same as has [sic] claimed in amended claim 1, *i.e.* docosahexaenoic acid and eicosapentaenoic acid. (*Id.*).

For the reasons presented below, the rejection, respectfully is traversed.

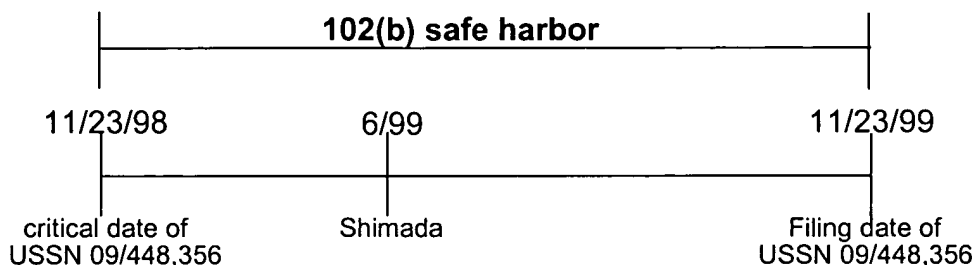
Shimada discloses the synthesis of steryl esters of PUFA with a lipase from *Pseudomonas* sp. (Page 712, Col. 2). To show that the disclosed enzymatic method is effective for the synthesis of steryl esters of PUFA, Shimada further disclosed in Table 3 the esterification of cholesterol, cholestanol, and sitosterol with a number of fatty acids, including docosahexaenoic acid and eicosapentaenoic acid. (Page 715, Col. 2 and Table 3).

Under 35 USC §102(b), “a person shall be entitled to a patent unless the invention was ... described in a printed publication in this or a foreign country ... *more than one year prior to the date of the application* for patent in the United States.” Thus, under the statute, there is a one year grace period or “safe harbor” from the effective U.S. filing date of the subject application in which certain activities (*e.g.*, publications) will not constitute anticipation. *See* MPEP 2133 at 2100-59.

The publication information in Shimada is set forth as follows: “Paper no. J9028 in *JAACS* 76, 713-716 (*June 1999*)” (*See* the first line under the Abstract) and “[Received September 24, 1998; accepted February 16, 1999]” (*See* Page 716, Col. 2, last line). The present

application, however, was filed in the U.S. on *November 23, 1999*, and was accorded that day as the date of filing. As Time Line-1 below shows, Shimada on its face, does not identify a date of publication more than one year prior to the U.S. filing date of the present application.

**Time Line-1**



Accordingly, Shimada is not prior art to the present claims under §102(b), and cannot be used to reject claims 1-4 in the manner set forth in the Office Action. Accordingly withdrawal of the rejection, respectfully is requested.

Claims 1-6 and 8 were rejected under 35 USC §103 as unpatentable over Novak WO 00/04887 (International Application No. PCT/CA99/00655) ("Novak"). (Paper No. 6 at 7).

For the reasons set forth below, this rejection respectfully is traversed.

Novak discloses a *composition* for use in preventing and treating cardiovascular disease and other disorders containing one or more phytosterols, phytostanols or mixtures of both, and one or more omega-3 polyunsaturated fatty acids (PUFA) or derivatives thereof. (Abstract). Novak discloses that:

To form phytosterol and/or phytostanol esters, one or more suitable aliphatic acids or their esters with low boiling alcohols are condensed with the phytosterol and/or phytostanol. A *wide variety* of aliphatic acids or their esters may be used successfully within the scope of the present invention and include *all aliphatic acids consisting of one or more alkyl chains with one or more terminal carboxyl groups*.



(Page 10, lines 9-13).

Novak further discloses various generic chemical structures for the aliphatic acids, *e.g.*, R1-COOH, HOOC-R2-COOH, HOOC-R3-(COOH)<sub>2</sub>, *etc.* (Page 10, line 15 to Page 11, line 14). In these structures, the respective R groups are defined in a number of different ways and include repeating units where n (the number of repeating units) is *e.g.*, 3-25 or 1-25. (*See e.g.*, Page 10, lines 17, 18, 23, 27, 28 and Page 11, lines 4, 10, and 14). Novak also discloses a list of 24 “preferred forms” of the aliphatic acid. (Page 11, lines 17-23).

Novak also discloses that the *composition* contains a *mixture* of the phytosterol and/or phytostanol and an omega-3 PUFA. (Page 3, lines 19-22, page 13, line 2, and claim 1). Novak also discloses that omega-3 PUFAs “for use within the composition of the present invention are selected from alpha-linolenic acid, EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) in the form of, *inter alia*, fatty acids, triglycerides, phospholipids, esters or free fatty acid salts.” (Page 12, lines 24-27 and claims 1, and 5-7).

In making the rejection, the Examiner asserted that that “[i]t would have been *obvious ... to prepare* additional beneficial compositions by selecting specific docosahexaenoic acid and eicosahexaenoic<sup>1</sup> acid from fatty acid taught by prior art.” (*Id.*). The Examiner acknowledged, however, that the “[i]nstant claims differ from the reference in claiming specific fatty acids *i.e.* docosahexaenoic acid and eicosahexaenoic<sup>2</sup> acid where as prior art teaches that

---

<sup>1</sup> We note that the Examiner uses the term “eicosahexaenoic acid” when referring to one of the fatty acids recited in claim 1. Claim 1, however, recites “eicosapentaenoic acid.” In this Response, we assume that the Examiner intended eicosapentaenoic acid when eicosahexaenoic acid was written. If this assumption is incorrect, the Examiner is requested to clarify this issue on the record.

<sup>2</sup> See footnote 1.

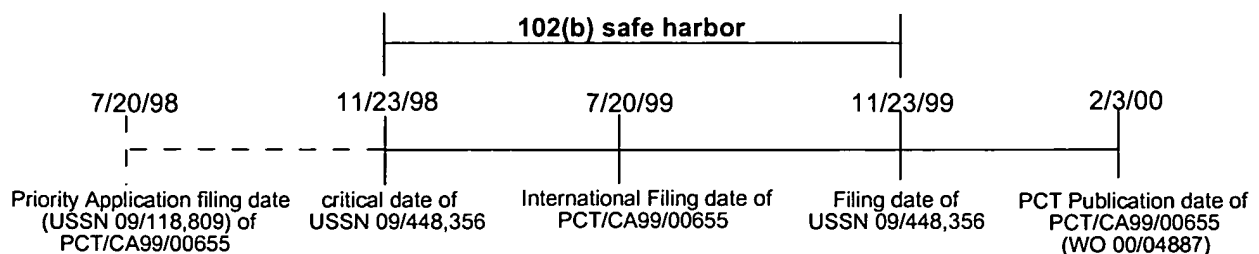
aliphatic acid may be selected from either straight chain of branched unsaturated or saturated fatty acids.” (*Id.*).

To fill the acknowledged gap, the Examiner appears to have relied upon the alleged knowledge of one skilled in the art and the broad generic disclosure of Novak. (*Id.*). The Examiner then concluded that “[t]here has been ample motivation provided by the prior art to prepare the instant invention by teaching unsaturated fatty acids and esters.” (*Id.*).

Initially, we note that once again a document relied on by the Examiner to reject the present claims in this Office Action is *not* prior art. Novak is a PCT publication that was published on “**3 February 2000.**” See Front page line (43) International Publication Date. Novak was filed as an International Application (PCT/CA99/00655) on 20 July 1999 (line 22) claiming priority to USSN 09/118,809 filed 20 July 1998 (line 30). (*Id.*). Accordingly, the Novak PCT publication is effective as prior art as of its *publication date, i.e., 3 February 2000.* As set forth above, the present application has an effective U.S. filing date of **November 23, 1999.**

As is well settled, whether a document is available as prior art under 35 USC §103 is determined with reference to the prior art definitions set forth in 35 USC §102. Accordingly, a review of §102 is in order with reference to Time Line-2 below.

#### Time Line-2



The Novak PCT publication is not prior under 35 USC §102(a) because it was neither patented (it is a PCT publication) nor published “before the invention thereof by the applicant.” As Time Table-2 clearly indicates, the present application has an effective U.S. filing date of November 23, 1999, which is *prima facie* evidence of a constructive reduction to practice *prior to* the February 3, 2000 Novak PCT publication date.

The Novak PCT publication is not prior art under 35 USC §102(b) because it was not “described in a printed publication ... more than one year prior to the date of the application for patent in the United States.” Again, the Novak PCT publication was published on February 3, 2000, whereas the critical date for the present application is November 23, 1998.

The Novak PCT publication is not prior art under 35 USC §§102(c), (d), (f), or (g) because these sections of the statute are clearly not relevant here.

The Novak PCT publication is not prior art under 35 USC §§102(e)(1) or (e)(2). §102(e)(1) is limited to (a) an application for patent published under §122 or (b) an international application *designating* the U.S. filed under the treaty defined in §351 (*i.e.*, the PCT) that was published under Article 21(2) of such treaty in the English language. Clearly, the Novak PCT publication is not an application for patent published under §122. And, an inspection of line (81) (*i.e.*, Designated States) of the front page of the Novak PCT publication indicates that the U.S. was *not* designated on the PCT Request. Accordingly, Novak is not available as prior art under §102(e)(1).

With respect to §102(e)(2), the Novak PCT publication is clearly not a *patent* granted on an application for patent by another filed in the U.S. before the invention by the applicant for patent. Because the Novak PCT publication is not a U.S. patent, it does not qualify as prior art under §102(e)(2).

For the reasons set forth above, the Novak PCT publication is not statutory prior art to the present claims. Accordingly, withdrawal of the rejection, respectfully is requested.

Notwithstanding the fact that the Novak PCT publication is not prior art to the present claims, we provide below our comments on the merits of the rejection.

Initially, we note that the rejection relies on a “selection of prior art” and “obvious to prepare” standards to reject the claims under §103. (See Paper No. 6 at 7). The statute, as well as, years of case law commands that the Examiner make the obviousness determination based on whether the “subject matter as a whole would have been obvious at the time the application was filed.” (See 35 USC §103). Thus, whether or not the claimed invention is a “selection of prior art” or would have been “obvious to prepare” is irrelevant to the required analysis. See *In re Wright*, 6 USPQ2d 1959, 1960, and 1961 (Fed. Cir. 1988).

Here, not only has the Examiner applied the wrong legal standard, which, it is submitted, is reason enough for withdrawal of the rejection (see *Ex parte Levengood*, 28 USPQ2d 1300, 1301 (B.P.A.I. 1993)), but the Examiner also has ***not even alleged*** that either docosahexaenoic acid or eicosapentaenoic acid fall within the scope of the genus disclosed by Novak. In the absence of such an allegation, the rejection has not met its burden required to support a *prima facie* case of obviousness. See *Ex parte Obukowicz*, 27 USPQ2d 1603, 1065 (BPAI 1992). For these reasons alone the rejection should be withdrawn.

The above deficiencies notwithstanding, the linchpin of the Examiner’s rejection rests on whether the two specific fatty acids recited in claim 1 (*i.e.*, docosahexaenoic acid and eicosapentaenoic acid) would have been suggested to one skilled in this art based on the disclosure in Novak. The rejection, however, is silent as to what specifically in Novak would

have lead one skilled in this art to use either docosahexaenoic acid or eicosapentaenoic acid as claimed.

The very passages of Novak cited by the Examiner recite that “*a wide variety* of aliphatic acids or their esters may be used” (Page 10, line 11), and that this group “*includes all aliphatic acids* consisting of one or more alkyl chains with one or more terminal carboxyl groups” (Page 10, lines 12-13). Even when Novak narrows this large genus to “preferred forms” (Page 11, line 17), the list includes 24 fatty acids, not one of which is either docosahexaenoic acid or eicosapentaenoic acid. (See Page 11, lines 19-23). Moreover, Novak characterizes these “preferred forms” simply as (1) straight-chain or (2) branched (3) unsaturated or (4) saturated fatty acids. The rejection provides no explanation of how such a generic disclosure of such a large genus of compounds or even the smaller 24-member subgenus would have led one skilled in this art to select the *two* specific fatty acids recited by claim 1. But that was the Examiner’s burden.

As is well settled, the recitation of a large genus does not *ipso facto* render obvious a species within that falls within that genus that is not specifically identified. See e.g., *In re Baird* 29 USPQ2d 1550, 1552 (Fed. Cir. 1994 (holding that a generic formula does not by itself necessarily render a compound encompassed by that formula obvious) and *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

Given the large genus defined by Novak and the lack of any explanation in the Office Action where the requisite motivation is found in Novak to lead one to select either docosahexaenoic acid or eicosapentaenoic acid, the rejection is insufficient as a matter of law. In fact, the rejection does not even explain how the recitation in Novak of “preferred forms” which does not include either docosahexaenoic acid or eicosapentaenoic acid would lead one to do as

the Examiner proposes. Moreover, Novak was clearly aware of omega-3 PUFAs in general, as well as docosahexaenoic acid and eicosapentaenoic acid specifically because these fatty acids were identified as part of the disclosed *composition*, *i.e.*, they were *mixed* with the esterified phytosterols or phytostanols. (See, Page 12, line 26 reciting “EPA and DHA,” page 13, line 2, Examples 1 and 2, and claims 1, 2, and 5-7)

Rather, given (1) the large genus disclosed in Novak, (2) the recitation of 24 specific, “preferred forms” of aliphatic fatty acids for use in the esterification of the phytosterol or phytostanol, and (3) the clear identification of both docosahexaenoic acid and eicosapentaenoic acid as reagents to *mix* with the previously esterified phytosterol or phytostanol, Novak would lead one skilled in the art away from selecting either docosahexaenoic acid or eicosapentaenoic acid as a fatty acid to use in the esterification reaction. In fact, the rejection does not even address why one would seek to esterify a phytosterol or phytostanol with either docosahexaenoic acid or eicosapentaenoic when one or both of them would subsequently be added as components in the disclosed *composition*.

In sum, for the reasons set forth above, the rejection is insufficient as a matter of law and fact to support a rejection under 35 USC §103. Accordingly, withdrawal of the rejection of claims 1-6 and 8, respectfully is requested.

Claims 1, 5, 6, and 8 were rejected under 35 USC §103 as unpatentable over Miettinen. (Paper No. 6 at 9).

For the reasons set forth below, this rejection respectfully is traversed.

Miettinen is summarized above.

In making the rejection, the Examiner asserted that Miettinen teaches a composition of  $\beta$ -sitostanol fatty acid ester or fatty acid ester mixture and a “fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol.” (*Id.*). The Examiner acknowledged, however, that “instant claims differ from the reference in claiming specific fatty acids *i.e.* docosahexaenoic acid and eicosahexaenoic<sup>3</sup> acid where as prior art teaches fatty acids especially containing approximately 2-22 carbon atoms.” (*Id.*).

To fill the acknowledged gap, the Examiner asserted that the “[i]nstant claims are a *selection of prior art* teachings. (*Id.* at 10).

The Examiner then concluded that “[i]t would have been *obvious ... to prepare* additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic<sup>4</sup> acid from fatty acid 2-22 taught by the prior art.” (*Id.*).

Like the Novak rejection above, the linchpin of this rejection is the Examiner’s unsupported contention that the “instant claims are a selection of prior art teachings” and that it would have been obvious to select either docosahexaenoic acid or eicosapentaenoic acid from the broad genus disclosed by Miettinen. Like Novak, this rejection provides insufficient evidence to support a *prima facie* case.

Initially, we note that the rejection relies on a “selection of prior art” and “obvious to prepare” standards to reject the claims under §103. (*See* Paper No. 6 at 10). The statute, as well as, years of case law commands that the Examiner make the obviousness determination based on whether the “subject matter as a whole would have been obvious at the time the application was filed.” (*See* 35 USC §103). Thus, whether or not the claimed invention is a

---

<sup>3</sup> See footnote 1.

<sup>4</sup> See footnote 2.

“selection of prior art” or would have been “obvious to prepare” is irrelevant to the required analysis. *See In re Wright*, 6 USPQ2d at 1960 and 1961 (Fed. Cir. 1988) *overruled on other grounds*.

Here, not only has the Examiner applied the wrong legal standard, which, it is submitted, is reason enough for withdrawal of the rejection (*see Ex parte Levengood*, 28 USPQ2d at 1301 (B.P.A.I. 1993)), but the Examiner also has ***not even alleged*** that either docosahexaenoic acid or eicosapentaenoic acid fall within the scope of the genus disclosed by Miettinen. In the absence of such an allegation, the rejection has not met its burden required to support a *prima facie* case of obviousness. *See Ex parte Obukowicz*, 27 USPQ2d at 1065 (BPAI 1992). For these reasons alone the rejection should be withdrawn.

Furthermore, as we noted above, Miettinen discloses that the  $\beta$ -sitostanol is esterified with “***different*** fatty acid ester mixtures” (Page 6, lines 28-29) that a methyl ester mixture of the fatty acids of “***any*** vegetable oil can be used in the reaction” (Page 6, lines 30-32 and Page 10, lines 22-23), and that “***any*** fatty acids which contain approx. 2-22 carbon atoms are usable” (Page 6, lines 33-34 and Page 10, lines 23-24). Moreover, we note that in four out of the five examples (*i.e.*, Examples 1-3 and 5) rapeseed oil was used and that Example 4 discloses the use of sunflower, soybean, olive, and corn oil as the fatty acid source. In none of these examples was an omega-3 PUFA specifically disclosed, let alone the two specific ones recited in claim 1 (*i.e.*, docosahexaenoic acid or eicosapentaenoic acid).

Thus, the rejection is silent as to how the broad generic disclosure in Miettinen would suggest either docosahexaenoic acid or eicosapentaenoic acid to one skilled in the art. The rejection is silent as to why one skilled in the art would be motivated to try either




docosahexaenoic acid or eicosapentaenoic acid given the absence of a discussion of omega-3 PUFAs in Miettinen as a source of fatty acids in the esterification process. The rejection is silent as to how the rapeseed oil featured in four out of the five examples in any way suggests either docosahexaenoic acid or eicosapentaenoic acid to one skilled in this art. This is the type of evidence required to support a rejection under §103.

Instead, the rejection relies on unsupported conclusions that the claims are “a selection of prior art” and that it “would have been obvious ... to prepare” the claimed compound using either docosahexaenoic acid or eicosapentaenoic acid. Thus, the rejection is not supported by the kind of specificity required to sustain a conclusion of obviousness. *Ex parte Humphreys*, 24 USPQ2d 1255, 1262 (BPAI 1992). (“The Examiner’s rejection is not *specific* as to *how* one of ordinary skill in the art would have found it (the claimed invention) obvious ....”). For this reason also, the rejection should be withdrawn.

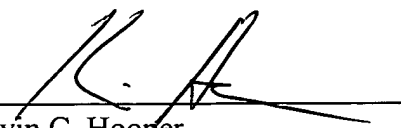
In sum, the rejection is insufficient as a matter of fact and law. Accordingly withdrawal of the rejection of claims 1, 5, 6, and 8 is requested.

In view of the foregoing, favorable action on the merits including reconsideration and withdrawal of each of the rejections, and allowance of all the claims, respectfully, is solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231, on February 28, 2001.

  
Kevin C. Hooper

Respectfully submitted,

By:   
Kevin C. Hooper  
Registration No. 40,402  
BRYAN CAVE LLP  
245 Park Avenue  
New York, NY 10167-0034  
(212) 692-1800